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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/853,544	05/10/2001	Miguel S. Barbosa	10624-051	7460

20583 7590 10/21/2003
PENNIE AND EDMONDS
1155 AVENUE OF THE AMERICAS
NEW YORK, NY 100362711

EXAMINER

PAK, MICHAEL D

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 10/21/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/853,544

Applicant(s)

BARBOSA ET AL.

Examiner

Michael Pak

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 July 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

1. The amendment filed 25 July 2003 (Paper No. 15) has been entered.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Applicant's arguments filed 25 July 2003 (Paper No. 15), have been fully considered but they are not found persuasive.

Claim Rejections - 35 USC § 112

4. Claims 13-17 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is a written description rejection.

The reason for the rejection has been set forth in the previous office action.

Applicants argue that a specification that discloses at least one method for making and using the claimed invention enables the entire scope of the claims and satisfies the enablement requirement of 35 USC 112. Applicants argue that the specification has not only identified each these markers including SEQ ID NO:57 (now SEQ ID NO:1, as amended) as being estrogen marker regulated marker. However, essential feature of the claimed method is the discovery that nucleic acid sequences

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which have not been identified by function such SEQ ID NO:1 can be used as regulated sequence of the estrogen modulation but the function of SEQ ID NO:1 is not known. For example at the time of the invention, NCI-CGAP (accession number AA747315, 1999), discloses a nucleic acid sequence which is identical to the claimed SEQ ID NO:1 but NCI-CGAP is a sequence which resulted from human genome sequencing and the function of the sequence is not known.

Applicants argue that the specification describes various ERM sequences by both structure and function and therefore meets the standard established for adequate written description of sequences by the Federal Circuit. However, essential feature of the claimed method is the discovery of nucleic acid sequences which have not been identified by function such SEQ ID NO:1 can be used as regulated sequence of the estrogen modulation but the function of SEQ ID NO:1 is not known. For example at the time of the invention, NCI-CGAP (accession number AA747315, 1999), discloses a nucleic acid sequence which is identical to the claimed SEQ ID NO:1 but NCI-CGAP is a sequence which resulted from human genome sequencing and the function of the sequence is not known. There is lack of written description for a method for genus of nucleic acid whose function is not known. The ability to regulate the nucleic acid not sufficient written description for the nucleic acid whose function is not known.

Claim Rejections - 35 USC § 102

5. Claims 13 and 15-17 remains rejected under 35 U.S.C. 102(b) as being anticipated by Mendelsohn et al.(US 5,728,534).

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The reason for the rejection has been set forth in the previous office action.

Applicants argue that Mendelsohn does not teach the method of identifying selective estrogen receptor modulators comparing contacting at least two cell and determining the levels of at least one estrogen-regulated marker in the cells in comparison with the levels of expression of estrogen regulated markers in cells following contact with estrogen. Mendelsohn teaches method of estrogen responsive compounds in vascular cells, cancerous cells, pre-cancerous cells, uterine cells, breast cells and non vascular-non reproduction cells (columns 2-3 and 10-11) using reporter responsive to estrogen (column 11-12). Mendelsohn assays two different cells simultaneously and different reporters (columns 8 and 9). Mendelsohn et al. teach the comparison of one cell expression with another cell expression (column 3, lines 44-66; column 4, lines 7-65; column 5, lines 1-21 and 60-67; column 6, lines 1-67; column 7, lines 1-67; column 8, lines 1-19). All the limitations of the claims are taught by Mendelsohn.

6. No claims are allowed.

7. Applicant's amendment necessitated any new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pak, whose telephone number is (703) 305-7038. The examiner can normally be reached on Monday through Friday from 8:30 AM to 2:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564.

The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Michael D. Pak

Michael Pak

Primary Patent Examiner

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16 October 2003